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Difficulty of clinical trials of acupuncture

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Abstract

We had retrieved and analyzed clinical evidence of acupuncture for low back pain using medical literature database (Medline and 医中誌) at 1995. There were 12 literatures in Japanese language journal and 13 literatures in English journal which had control group. Results from trials, which used sham acupuncture as placebo control, failed to prove specific effect of acupuncture. Evidence from the other types of trials, which compared standard care plus acupuncture with standard care alone and compared acupuncture with no treatment control, suggested that acupuncture was effective.

Systematic reviews (SRs) on acupuncture for LBP were published in 1998 (Ernst) and 1999 (Tulder). In the former SR, data was synthesized, but meta-analysis failed to show specific effect of acupuncture with sham acupuncture control. The latter SR reported strong heterogeneity among the trials. Therefore, meta-analysis was avoided and qualitative assessments were performed. And data did not show advantage over any types of control. Authors of both SRs regarded that quality of trials were generally low.

Quality of clinical evaluation of acupuncture in early stage was regarded as poor on study design. Their attempt to introduce research methodologies into acupuncture study was not easy. Origin of research methodology is clinical pharmacology and that is characterized by nature of drug therapy. Needless to say, acupuncture therapy is one of complex intervention and appropriate parameter for prescription of acupuncture procedure has not yet been clearly defined.

Methodological issue focused on appropriate interventions on acupuncture trial had been addressed to probe specific effect of acupuncture.

Thereafter, at 2005, two SRs Manheimer (2005) and Furlan (2005), on acupuncture treatment for LBP were published and their results succeed to prove specific effect of acupuncture. We had believed that progress in appropriate setting of intervention make reduce type II error and we believed that we might free from the difficulty of specific effect of acupuncture.

Regrettably, evidence is not proving the specific effect of acupuncture on low back pain at present. What should we do in order to break the bottleneck?

Key words: *Acupuncture, Specific effect, Low back pain, Research methodology, Medical technology assessment*

I. Introduction

We had retrieved and analyzed clinical evidence of acupuncture for low back pain using the medical literature database "Medline" and "Igaku Chuo Zasshi (Japana Centra Revuo Medicina)" ending at 1995[1)]. We had detected 11 papers in Japanese language journals and 13 papers in English journals which had control groups. Results from these trials, which used sham acupuncture as placebo controls, failed to prove any specific effects of acupuncture. Evidence from the other types of trials, which compared standard care plus acupuncture with standard care alone and compared acupuncture with no treatment control, suggested that acupuncture is effective.

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The first systematic reviews (SRs) on acupuncture for Low Back Pain(LBP) were published in 1998(Ernst)[2] and 1999(Tulder)[3]. In the former SR, data was synthesized, but meta-analysis failed to show specific effects of acupuncture with sham acupuncture controls. The latter SR reported showed large heterogeneity among the trials. Therefore, meta-analysis was avoided and qualitative assessments were performed. And data did not show advantages over any types of control. Authors of both SRs concluded that the quality of the trials were generally low.

II. Development of research methodology on acupuncture.

Considering the literatures the quality of clinical trials of acupuncture in early stages was regarded as poor. Attempts to introduce research methodologies into acupuncture studies had not been easy. Origins of research methodology developed from clinical pharmacology and it is characterized by the nature of drug therapy. Variables of drug therapies can be simply defined by dose. Needless to say, acupuncture therapy is a very complex intervention. STRICTA (STandards for Reporting In Clinical Trials of Acupuncture),[4] that is required for reporting clinical trials of acupuncture, consists of twenty parameters to reproduce acupuncture interventions.

Methodological issues focused on appropriate interventions for acupuncture trials had been addressed to show the specific effects of acupuncture[5,6]. It appeared that methodological difficulties on clinical trials of acupuncture were eliminated. Thereafter, in 2005, two SRs conducted by Manheimer[7] and Furlan[8] on acupuncture treatment for lumbago were published and they succeeded in proving some specific effects of acupuncture. We had believed that progress in appropriately setting-up interventions reduced type II errors and would reduce problems associated with the specific effects of acupuncture.

III. Failure to prove specific effects of acupuncture in phase III trials.

We anticipated that progress in design intervention achieved the breakthroughs in clinical studies of acupuncture. The phase-III trials performed by insurance unions of Germany had been paid attention to by researchers. Theoretically, if the sample size of clinical trials is increased, the sensitivity of the trial will also increase. Surprisingly, although the sample size increased, the detection of the effect was not realized in most of the German studies. How can we interpret this discrepancy?

In the German studies, large numbers of participants were recruited among large numbers of sites, which were compelled to join the study. And it meant large numbers of researchers were involved in the study.

Those should lead trial into some difficulty of extreme multicenter study. Gaus (1995)[9] pointed out general considerations for studies on unconventional therapy.

- Each practitioner can recruit only a few patients for a study. Therefore, many practitioners must try to cooperate, but all problems of an extreme multicenter study will appear.
- It is difficult to undertake the very same procedures in all participating doctor's offices in order to get comparable groups and account for small variations within the groups. A small variance within groups is necessary to make the study powerful.
- The more physicians who have to cooperate in a study, the more difficult it is to organize and manage the study procedures.

In small sample size phase II trials, it is easy to control the process of trial and interventions in detail. For example, a phase III trial[10] (Brinkhaus 2006) was conducted in 30 outpatient centers, and acupuncture interventions were performed by 45 physicians who had been trained 350 hours (median; range 140-2508). But, it was difficult to control for clinical skills when research group members were recruited. Treatment skills is a personal ability, it is not simple to measure. Clinical skills may be one of the most difficult areas which ideally should be controlled on acupuncture trials and medical service.

Until now, research methodology has been the focus on procedure of trial in most clinical studies. Researchers have not thoroughly considered the impact of the personal differences among practitioners. Regrettably, evidence is not proving the specific effect of acupuncture on low back pain at present. Our challenge is to continue establishing the new methodology of clinical studies. The important aspects of acupuncture clinical skills that depend on the human ability of the clinician.

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